

REMARKS

First of all applicants wish to thank the Examiner for the courtesies extended to the undersigned attorney and to inventor Dr Thomas Webster during a telephonic Examiner's interview conducted on May 13, 2008. During that interview applicants discussed the teachings of the prior art reference, US patent No: 6,270,347. More particularly, applicants noted that the '347 patent was directed to nanostructured ceramics and composites thereof, but failed to disclose nanostructured polymeric materials. Furthermore, applicants noted that one of ordinary skill in the art would readily appreciate that different materials (e.g., ceramics vs polymeric materials) behave very differently upon implantation into an animal. Accordingly, applicants noted that one of ordinary skill in the art would not have a reasonable expectation that the results reported in the '347 patent would hold true for different materials, including polymeric materials. Lastly, applicants noted that the procedures disclosed in the '347 patent for preparing nanostructured ceramic materials are uniquely suited to that material. Accordingly, the '347 patent fails to disclose how to make a nanostructured polymeric material, even if one was motivated to do so.

Applicants acknowledge the Examiner's finding that claims 2 and 4 would be allowable if rewritten in independent form. Accordingly applicants have amended claim 2 to place the claim in independent form. Claim 4 depends from claim 2 and accordingly applicants respectfully submit the amendment to claim 2 places claims 2 and 4 in condition for allowance.

Claims 1, 3, 5, 7-19 and 33-42 stand rejected under 35 USC §103 as being unpatentable over Webster (US Patent No. 6,270,347). Applicants respectfully traverse this rejection.

As applicants emphasized during the telephonic interview, the Webster '347 patent is limited to compositions comprising nanostructured ceramics for oethopaedic/dental applications. As noted by the Examiner, the '347 patent also discloses composite materials that comprise a nanostructured ceramic and "one or more natural or synthetic polymers, other than a peptide, in addition to the nanophase materials" (see column 5, lines 31-35; emphasis added). Accordingly, the '347 patent is limited to nanostructured ceramics and fails to teach or suggest a composition that comprises a nanotextured polymeric material as claimed in the present invention.

Furthermore, the '347 reference teaches a procedure for forming nanostructured ceramic materials that is not applicable for forming other nanostructured materials. More particularly, the preparation of the nano-grained ceramic materials of the '347 patent is

conducted by forming precipitates of the ceramic materials using controlled reactions. There is no disclosure relating how to prepare polymeric materials that display nano-textured surfaces. Accordingly, not only does the '347 patent fail to teach or suggest the desirability of a composition comprising nano-structured polymeric materials, the reference is devoid of any guidance of how to prepare such polymeric materials that display nano-sized surface features and a surface roughness of about 50 nm or greater.

Applicants also respectfully submit that one would not be motivated to prepare a composition comprising a nano-structured polymeric material based on the results disclosed in the '347 patent. First of all, one of ordinary skill in the art appreciates that cells will respond differently (i.e., display different properties) based upon the material that is placed in contact with those cells. Therefore, one of ordinary skill in the art would have no reasonable expectation that a polymeric material could substitute for ceramic materials to produce similar results as those obtained with ceramic materials.

In support of such a statement applicants have attached a scientific publication (Exhibit A; Kim et al, Biomaterials 27 (2006) p 1399-1409) that demonstrates that a polymer by itself induces minimal amount of *in vitro* osteoblast growth or alkaline phosphatase, and calcium deposition (all indicators of bone growth) compared to a nano ceramic (hydroxyapatite, "HA") composite when place in contact with cells *in vitro* (see Fig. 4). Similar results were obtained upon implantation *in vivo* (see Figs. 6-8, and text at page 1406, second column lines 5-7). Furthermore, the authors report that the composites presenting a higher exposure to the nano ceramic materials performed the best (see Figs. 4 and 8). Accordingly, this paper specifically addresses the ability of polymeric materials to substitute for ceramic materials and supports the more general known principle that cells will respond in a highly variable and unpredictable way when contacted with a novel material relative to another tested material. Therefore, the results reported in the '347 patent would not provide a reasonable expectation of success for duplicating the desirable results reported in the '347 patent when using polymeric materials instead of ceramic materials.

The Examiner contends that one of ordinary skill in the art would have been motivated to optimize the specific surface roughness of the implant, thus leading to the presently claimed composition. However, even if applicants accept that statement, the '347 patent only discloses modified ceramic surfaces and is devoid of any suggestion regarding the modification of any polymer component that is also present in the composition. The presently claimed invention requires a nanostructured polymeric material as an element of the composition. The '347 patent simply fails to consider or suggest that a polymer surface could

be modified to display nanotextured surface. As noted above one of ordinary skill in the art would not have a reasonable expectation of success duplicating the results obtained for nanostructured ceramic materials when using polymeric materials. The results obtained by applicants using polymeric materials that were prepared to display nano-sized surface features, and a surface roughness of about 50 nm or greater are surprising and unexpected. Such properties are the hallmark of non-obviousness.

The discovery of a new effective range is nonobvious when the results obtained using the new range are unexpectedly good. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As disclosed in the present specification, and the Declaration by Dr. Webster (submitted with the 11/27/07 response and providing further experimental data), polymeric surfaces displaying surface features having dimensions less than 100nm display unexpected properties relative to the properties displayed by polymeric compositions having submicron or larger surface features. When an applicant demonstrates substantially improved results and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary. *In re Soni*, 54 F3d 746 (Fed. Cir. 1995). The existence of novel or superior unexpected properties, undisclosed by the prior art, weighs heavily in favor of a conclusion that the claimed composition is not obvious. *Air Products and Chemicals, Inc. v. Chas S. Tanner Co.*, 219 USPQ 223, 231 (SC 1983); *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Applicants have discovered the surprising result that polymeric compositions that display surface features having a dimension of less than 100nm have dramatically improved desirable properties relative to polymer surfaces displaying submicron surface features. There was simply no reasonable expectation that polymeric materials would exhibit such properties prior to applicants' invention.

Accordingly the '347 reference fails to teach or suggest that a composition comprising a nanostructured polymeric material as its active agent would be desirable. Nor does that reference enable the preparation of such compositions. Therefore, applicants respectfully submit that the invention of claims 1, 3, 5, 7-19 and 33-42 are patentably distinct over the teachings of the Webster '347 patent.

Furthermore, applicants note that claim 37 specifically excludes the inclusion of ceramic materials in the presently claimed invention. All compositions disclosed in the '347 patent comprise a ceramic component (i.e., alumina, titania or hydroxyapatite). The '347 patent fails to teach or suggest an implant that lacks the ceramic supporting structure. There is simply no suggestion in the '347 patent that an implant lacking such material could be

prepared and have the requisite strength required for the uses disclosed in the present application. As demonstrated by the Kim et al reference (attached as Exhibit A) such a composition lacking a ceramic component produced only minimal amounts of new bone growth.

Accordingly, Webster fails to teach or suggest the present invention and applicants respectfully request the withdrawal of the rejection of claims 1, 3, 5, 7-19 and 33-42 as being obvious over the teachings of Webster (US Patent No. 6,270,347).

Claims 1-12 stand provisionally rejected based on nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 7-20 of co-pending Application No. 10/362,148. In addition, claims 1-12 and 18 stand provisionally rejected as being unpatentable over claims 1-11 of co-pending Application No. 10/793,721. Applicants respectfully request that these rejections be held in abeyance until the Examiner makes a finding of patentable subject matter.

The foregoing claim amendments and remarks are believed to fully respond to the Examiner's rejections, and the claims are believed to be allowable over the cited prior art. If any further discussion of this matter would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,



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